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Egypt

Biotechnology

Annual Agricultural Biotechnology Report

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Report Highlights:
Egypt is a leading country in the Middle East/North Africa region in the development and acceptance of agricultural biotechnology. it consumes large quantities of biotech products such as corn and soybeans. The country has a large and highly sophisticated agricultural research center, which expects to start growing BT cotton by the year 2006.

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SECTION I. EXECUTIVE SUMMARY

Egypt leads the Middle East and North Africa region in the development and acceptance of agricultural biotechnology. The Ministry of Agriculture is a strong supporter of biotechnology. Egypt is a large consumer of agricultural products (such as corn, soybeans, and soy meal) derived through modern biotechnolgy and imported from the United States and Argentina. The government continues to maintain a general import policy that allows imports so long as the product imported is also consumed in the countries of origin.

Egypt has not produced any commercial biotechnology crops. However, the Agricultural Genetic Engineering Research Institute (AGERI) is developing a number of GM products for commercialization by working with leading biotechnology companies and universities in the United States. These crops are tuber moth-resistant potatoes, virus-resistant squash and tomatoes, corn borer-resistant maize and drought-tolerant wheat. Through collaboration with Monsanto, AGERI has developed an insect-resistant long-staple GM cotton strain.

Despite the relatively advanced research and development Egypt has made in agricultural biotechnology, public awareness about biotechnology is very limited and often either misconceived or misunderstood. Egyptian government leaders recognize the importance of biotechnology as a tool for national and global development and have set excellence in biotechnology and genetic engineering as a national goal.

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

Genetic engineering programs in Egypt started in 1990. In 1992 a cooperative research agreement was reached between AGERI and ABSP (Agricultural Biotechnology for Sustainability Productivity Project) to develop Egypt's agricultural system and make it more friendly environment. Teams of scientists from both Egypt and the United States were established to address specific commodity constraints and policy issues such as biosafety and intellectual property rights, and management and networking within the project.

To date, Egypt has not produced any commercial biotechnology crops. Four crops are approaching the stage of commercial release:

1- Potatoes, engineered to resist infestation by potato tuber moth, developed through a collaboration involving AGERI, the ABSP project, and the International Potato Center's (CIP) regional office in Egypt. Varieties of importance to Egypt have been transformed and are being field-tested. The project is at the threshold of commercialization. The mechanism to move the tuber-moth-resistant potatoes from the research arena to the commercial arena is still being explored and will be the focus of future efforts.

2- Squash plants, resistant to a major viral pathogen, resulted from cooperation between two Egyptian research institutes, AGERI and the Horticulture Research Institute (HRI), and the ABSP project.

3- Yellow and white varieties of maize, modified for resistance to stem borers, independently produced by two international companies. These were the first GMOs imported into Egypt for the purpose of field trials.

4- Cotton, Egypt may be on the verge of launching the country's first commercially grown genetically modified crop, a strain of cotton that could save the industry millions of pounds every year by boosting output and virtually eliminating chemical crop spraying. AGERI has found a commercial partner in the Monsanto Company, the US-based producer of the world No. 1 herbicide, and anticipates Egypt will be able to

start growing GM cotton by 2006. The new cotton crop will contain a gene purchased from Monsanto that makes the plants resistant to certain insects, but it will retain its unique Egyptian characteristics in every other respect. AGERI has also cooperated with Cotton Research Institute (CRI) to insure that the new plants produce the sought-after long staple fibers for which Egypt known. The selection was done by the breeders, making the collaboration a multi-disciplinary approach. The new cottonseeds contain a patented gene. Any future user of the gene must pay a royalty to Monsanto, but advocates say that increased output, along with the amount farmers will save on chemical fertilizers, will more than cover the price of the switchover.

Scientists in Egypt are in the process of producing drought-tolerant wheat by transferring a gene from barely into a local wheat variety. Trials are also being conducted on rice by using tissue culture techniques at the Rice Research and Training Center in Sakha to overcome sterility in some japonica crosses, and to fix inherited traits such as protein content and starch characteristics.

Research on the use of biofertilzers to increase rice yields in Egypt has demonstrated the beneficial effects of the blue-green algae, Cyanobacteria, for rice growth and yield increase. The Ministry of Agriculture has set up a program for the production of sufficient Cyanobacteria inoculum, to cover an area of about one million feddan (400,000 ha).

Egypt's biomass potential is approximately 23 million tons of agricultural residues and 4.88 million tons of animal waste. One-third and one-tenth of the fuel requirements of rural Egypt are met from crop residues and animal droppings, respectively. If proper technology is applied to convert biomass into biofuel, the same energy requirement could be met and consequently, an additional 910 million tons could be diverted to animal feed. Biogas technology was sought as an effective means to convert agricultural biomass and animal droppings into biofuel and manure. A research program initiated in the 1950's on an experimental scale has grown into an ambitious one through the FAO-sponsored project "Biogas and Rural population". Several small-scale plants have been set-up in different regions to study their socio-economic implications.

The process for securing commercial release approval for crops genetically engineered outside of Egypt has an added step. The applicant must first obtain a permit for importing the initial seed material from the Supreme Committee for Food Safety (SCFS), Ministry of Health. The permit is then presented to the National Biosafety Committee (NBC) and the Seed Registration Committee (SRC), after which the seed is imported into the country. From this point forward, the remaining steps in the approval are exactly the same as for GMOs developed within Egypt.

Procedures for commercializing GMO crops were established in 1998 by Ministerial decree No. 1648. For varieties produced within Egypt, the process is as follows:

- The applicant completes a permit application form providing details of the genetic material introduced, the process used for inserting it, and other relevant information. The applicant also provides data from food and feed safety studies and evidence supporting a determination of low or negligible environment risk. Where applicable, the applicant provides documents indicating approved of similar GMO's for release in their country of origin.

- The application is submitted to the NBC, which, after examination and approval, forwards it to the SRC for their preliminary approval to proceed with standard field trials conducted at several locations. The SRC assigns a team of qualified inspectors drawn from relevant ARC units and/or private certified laboratories to supervise

cultivation, ensure adherence to any biosafety requirements, confirm the new phenotype, and evaluate agronomic performance.

- The NBC has the right to confirm the nature of the genetic modification by taking samples from the field for molecular analysis.

- After successful completion of the field trials and submission of a report to the NBC, the NBC authorizes the applicant to submit an application to the SRC for final approval to commercially release the new variety. Pending this, three-year seasons of agronomic performance trails are conducted under the supervision of the SRC.

Egypt is not a food aid recipient and not expected to be in the near future. Egypt is also in the final stages of developing its own biotechnology products. The government continues to maintain a general import policy that allows imports so long as they are also consumed in the countries of origin.

SECTION III. BIOTECHNOLOGY POLICY

Responsible government ministries and their role

The Ministry of Agriculture is a strong supporter of biotechnology, and its AGERI is developing a number of GM products for commercialization by working with leading biotechnology companies and universities in the United States. An-interministerial committee chaired by the Minister of Agriculture is responsible for formulating policy on biotechnology.

AGERI is the main research body of agricultural biotechnology in Egypt. It is a part of the Agricultural Research Center (ARC), which is directed by the Ministry of Agriculture. Although there has been some collaboration with international firms in the private sector, AGERI has relied primarily on its own scientific resources. This explains the relatively slow progress of biotechnolgy in Egypt. AGERI has been working on a wide range of species, primarily on developing pest and disease resistance and drought tolerance. Species being worked on have included potato, tomato, cotton, corn, fava bean, cucurbits, wheat, banana, and date palm. It has received assistance from USAID in the past and this has encouraged some joint research with U.S. agricultural institutions.

Egypt does not have national legislation on biotech, but there is a general government policy regarding the importation of genetically modified crops into Egypt. At present, there is no requirement to label GM food products. AGERI has high creditability with countries of the region in explaining the benefits of biotechnology, and officials from all over the region have been astonished and pleased to learn about Egyptian advances in biotechnology. Egypt is a convincing example of how developing countries will benefit from biotechnology.

Table 1. Laboratories Located at AGERI

Name of Laboratory
Molecular Plant Pathology
Molecular Manipulation and Gene Transfer
Plant Molecular Biology
Molecular Genetics and Genetic Mapping
Micro Propagation Technology
Plant Cellular and Molecular Genetics
Immunology and Diagnosis

Name of Laboratory
Protein Nucleic Acid Sequencing and Synthesis
Gene Expression
Biocomputer and Network

The Ministries of Health, Agriculture, and Higher Education and Scientific Research control almost all food policy decisions in Egypt. In addition, the Ministries of Foreign Trade and Industry, Supply and Home Trade, and Finance control the flow of food imports and exports through Egypt.

Ministry of Agriculture: The Ministry of Agriculture is responsible for arranging events and seminars that would explain biotechnology to farmers and to the public. It works closely with the Ministry of Health and is the main authority responsible for food cultivation issues. Within the Ministry, the Central Administration for Seed Testing and Certification (CASC) controls, tests, and registers new plant varieties. There are three bodies responsible for food safety and control: the Reference Labaratory for Safety Analysis of Food of Animal Origin (RLSAFAO); the Central Labaratory for Food and Feed (CLFF); and the Food Biosafety System (FBS).

Ministry of Health: The Ministry of Health has different specialized departments and is charged with maintaining and improving the overall health of the population. Its responsibilities include: approving all food products for sale in Egypt, supervising food quality, regulating the use of preservatives in foods, and ensuring that products are labeled properly with expiration dates.

The ministry has the following committees and organizations:

- The Supreme Committee for Food Safety ensures the safety of food production and consumption and controls food import permitting.
- The National Organization for Drug Control and Research overseas pharmaceutical research and controls distribution.
- Food Safety and Control General Directorate (FSCGD)
- The Central Public Health Laboratories (CPHL)
- The National Institute of Nutrition (NIN)

Ministry of Foreign Trade and Industry (MOFTI): The ministry executes its activities through the following organizations:

- The Egyptian Organization for Standardization and Quality Control (EOS) sets the standards for food and industrial products whether imported or locally produced.
- The General Organization for Export and Import Control Authority (GOEIC)

Ministry of Environment: The Egyptian Environmental Affairs Agency ensures implementation of the Environmental Protection Law in Egypt.

Ministry of Higher Education and Scientific Research: The ministry plays a complementary role to the Ministry of Agriculture. They both feed information to the Ministry of Health. If technology appears to be harmful, the ministry would oppose it. The main research body of the ministry is the NRC. The center arranges regular seminars that are attended by officials in government agencies. It has held seminars on food biotechnology in the past.

Ministry of Supply and Home Trade: Control the flow of imports and exports through Egypt; significant influence on import and export of GM food and agricultural products.

In 1993, Al-Azhar University established a Regional Center for Mycology and Biotechnolgy to develop applications for fungi and biotechnology. Currently it carries out research in different subjects including biosynthesis of new forms of antimicrobial agents, metabolic regulations of mycotoxines production, fungi and allergy and fungal biotechnology, and biodegradations and biotransformations and enzymes.

Role and membership of biosafety committee

Egypt has a fairly well-advanced biosafety system, and it has ratified the Cartagena Protocol. In 1995, the Ministry of Agriculture formally instituted Egypt's national biosafety system. A National Biosafety Committee (NBC) was established and included representatives from the ministries of agriculture, education, industry, health, environmental affairs, private sector, policy makers, and consultants knowledgeable in polices and applicable laws, and non-technical members. The initial committee consisted of 10 members. Subsequent appointments expanded membership to 30. Current members include seven representatives from the ministries of Agriculture, Health, Environment, Industry, and Commerce; one representative from the Egyptian Academy of Science and Technology; 12 members from academic institutions; one attorney, eight people from government research institutes, and one seed expert. Based on area of expertise, members are appointed to one of three subcommittees that specialize in agriculture (crops), environment (biopesticides, biofertilzers, agents for bioremediation), and health (pharmaceuticals, human, and veterinary vaccines).

The committee is responsible for ensuring the safe use of biotechnology products and facilitating access to modern biotechnolgy generated abroad. The system involves several ministries, organizations, and government agencies involved with the importation, exportation, and local production of natural products. The committee establishes policies and procedures to govern the use of modern biotechnology. This includes publishing the National Biosafety Committee guidelines (NBC guidelines) to be followed at the national level. The committee also provides technical advice to the regulatory authorities and institutions responsible for the development of biotechnology in Egypt. The guidelines describe the modalities of use, handling, transfer, and testing of GMOs. They address laboratory practices, greenhouse containment, and small-scale field-testing.

Duties of the committee include formulating, implementing and updating biosafety guidelines, conducting risk assessment, issuing permits, coordinating with national and international organizations. The biosafety guidelines are not legally binding. They have only advisory status. There are no details regarding review, decision making, and reporting processes, and they have not been well publicized within the country. Nevertheless, the guidelines have functioned since 1995, with 23 permits for field trials issued and four GM crops moving toward commercial release.

The activities covered by the biosafety guidelines include risk assessment, determination of the level of safety concern (LSC) for parental organisms, and determining the effect of genetic modification on level of safety concern.

There is also an Institutional Biosafety Committee (IBC). The NBC requires that all institutions conducting R-DNA research assemble an IBC. The IBC is responsible for insuring that the R-DNA is carried out in full conformity with the provision of the NBC guidelines. The IBC may establish additional procedures as deemed necessary to govern its institution's

activities. The IBC designates a biologic safety officer (BSO) that meets the requirements of NBC and who should be familiar with biosafety.

Political factors that may influence regulatory decisions

Despite the relatively advanced research and development Egypt has made in agricultural biotechnology, public awareness about biotechnology is very limited and often either misconceived or misunderstood. Egyptian government leaders recognize the importance of biotechnology as a tool for national and global development and have set excellence in biotechnology and genetic engineering as a national goal. The Egyptian government made a strategic decision that the first commercialized GMOs would be products of Egypt's AGERI/NRC, rather than imported products grown commercially in their country of origin. In this way, the public's introduction to biotechnology would be in the form of preferred local varieties engineered to overcome local diseases or pests problems-products developed at home to benefit Egyptian farmers, growers and consumers.

Problems cited for the slow passage of GM crops from experimental, to trial, to commercial stage include the lack of capacity to negotiate licenses to use genes and research techniques patented by others, especially for crops with export potential. In addition, there are difficulties in meeting regulatory requirements and a lack of effective public commercialization modalities and working extension networks. One of the problems is the lack of a dynamic private sector to take technologies to the farmer. It has also been estimated that regulatory costs might exceed the costs of research and experimentation needed to develop a given GM crop, which is the major problem in releasing such crops to the market.

Environmental requirements

Egypt has no required environmental tests for GMO products.

Field-testing of biotechnology crops

A standard permit application form is used to request NBC approval of a proposed greenhouse study or field test. Upon submission of the application, all members of the appropriate subcommittee are given copies, and one member is designated the principal investigator. The principal investigator, who may consult with other subcommittee members, is assigned to thoroughly review the application, visit the field test location, inspect the facilities, and submit a report to the NBC. The proposed release is then discussed at a meeting of the full NBC, where a decision is made to issue or deny the requested permit. Where a Committee member is the applicant or had been involved in the research leading to the GMO to be considered, that member does not vote in the application.

Applications to field test genetically modified plant material are submitted to the chair of the NBC. Genetically modified material to be imported requires an import permit that must be obtained in advance from the Supreme Committee on Food Safety, Ministry of Health and Population. Requests should be made a minimum of eight weeks prior to the proposed initiation of the importation or field test.

The NBC, as the lead agency, sends duplicate copies to secondary agencies for their assessment (i.e. Supreme Committee on Food Safety), as applicable. Reviews from the secondary agencies are returned to the NBC, and a final assessment is performed. From this, a decision is made whether to authorize the field test. Mitigation procedures are taken to protect confidential information, such as exact trial sites, plasmid maps, and exact genetic change. Other information may initially be designated confidential, however its

confidentiality is subject to provisions in the Access to Information and Privacy Act. Field-test permit applications must describe the plant species modified to exhibit a specific trait, to be tested at a specific location in a specific year.

In Egypt, approval by the NBC to conduct a field test does not require the applicant to submit a report at its conclusion. During seed registration trials, an appointed team of inspectors carries out monitoring. As the purpose of the trial is to evaluate variety performance, monitoring is conducted primarily to ensure compliance with biosafety requirements, not to collect biosafety data.

The biosafety system was developed in a way in which components are added only as they become necessary. For example, testing requirements for GMO seed certification were not clarified until the first applications for commercial release were submitted to SRC.

Table 2. Crops under field trials

Crop
Cucumber
Maize (Zea Mays)
Maize
Melon
Musk melon
Musk melon, Squash
Potato (Solanum tuberosum)
Cantaloupe
Recombinant DNA construct
Squash
Sugar Cane (Saccharum officinarum)
Tomato (Lycopersicon esculentum)
Wheat

Labeling requirements for packaged foods or feeds

No decisions on the labeling of GMO-based food products have been made, as those products are not yet being sold in supermarkets. Egyptian law does not require that biotech crops or products that are utilized, consumed, or imported have a special approval or labeling, but the governmental authorities deal with biotech products as it deals with non-biotech products. In addition, there is no approval needed for importing biotech products. Egypt requires restrictive labeling for imports of food products in general, but there is no special labeling requirement for biotech packaged or non-packaged products.

Trade barriers that hurt U.S. exports

U.S. agricultural exports to Egypt currently face no import restrictions as a result of policy towards agricultural biotechnology. However, this could change if organizations such as the Ministry of Environment continue on their negative and often confusing rhetoric about the "potential risk" of agricultural biotechnolgy and the need for Egypt to "align itself with Europe on this issue rather than the United States". The Ministry of Environment praises the European regulatory regime on agricultural biotechnology, which requires traceabilty, and labeling of products that are derived through modern biotechnology.

Pending legislation that may affect U.S. exports

The Ministry of Environment is taking the leadership role in drafting Egypt's biosafety legislation and implementation regulations, which may complicate trading with Egypt. However, the draft biosafety legislation, which was scheduled to be presented to the Parliament this year, has been put on hold due to disagreements between the Ministry of Environment and other members of the biosafety committee, especially the Ministry of Agriculture.

SECTION IV. MARKETING ISSUES

Market issues

There are mixed feelings about the benefits of food and agricultural biotechnology. While some people acknowledge that biotechnology may improve food quality and availability, they are also concerned about the cost of the technology. There is a belief that biotechnology could drive up prices for raw materials, ingredients, and seeds. In addition to the price, there is concern with religious beliefs. Political attitudes in Egypt do not currently favor the U.S. in general, which severely reduces consumer interest in products from the U.S. However, some food manufacturers already use U.S. ingredients. Because they are not required by law to reveal this to customers, they choose not to, fearing it will hurt sales.

Studies useful for the U.S. export community or U.S. policy makers

- Biotechnology market research: Global Based Initiative (GBI), a report for the GBI participants; Promar International, Morgan & Myers, & Roper Media and public Affairs (NOP World), August 2004.
- Analysis of a National Biosafety System: Regulatory polices and Procedures in Egypt, Magdy Madkour, Amin El-Nawawy, and Patricia Traynor, Report prepared by AGERI and International service for National Agricultural Research (ISNAR), country report 62, 2000.
- Agricultural Biotechnology Support Project (ABSP), Egypt Project Final Report. A project submitted by Dr. Johan Brink, supported by USAID and implemented by Michigan State University, 2002.

SECTION V. CAPACITY BUILDING AND OUTREACH

USDA funded capacity building and outreach activities

USAID financed the AGERI state-of-the art office complex building in 1990. In 2002, post organized a workshop for more than 15 regional Codex committee members, which was attended by Egyptian media and TV people. Post also developed a multi-year regional outreach program in cooperation with AGERI's Biotech Information Center in 2003, and a number of activities was implemented to better inform stakeholders in the region about the benefits of agricultural biotechnology. Following are some of these activities:

- The first activity of this program was held in February 2004 for Egyptian journalists who are the primary conduit to informing the public. Another four journalists participated in a USDA agricultural biotechnology-training program in the U.S. in September 2005.
- Post organized a successful three-day regional agricultural biotechnology conference in December 2004 in Cairo, Egypt in cooperation with the Egyptian Office for Standardization and Quality Control and the Ministry of Agriculture and a number of other stakeholders in this debate. Representatives from standard-setting organizations and

Codex officials from 14 countries including Egypt attended the three-day conference, which provided an excellent forum for discussion on the benefits of agricultural biotechnology.

- AGERI held a one-day conference on foods derived through agricultural biotechnology as part of its outreach efforts to promote the use and benefits this technology offers. The conference was co-sponsored by Egypt's Academy of Scientific Research and Technology. FAS funded the participation of two speakers (one from the UK and one from the USA).

Future strategies

Post is planning to conduct other activities such as inviting a group of scientists and decision makers to visit U.S. biotechnology facilities to discuss the most recent developments in this field. Post will also organize a regional workshop on biosafety issues as an educational program for decision makers in the region.

SECTION VI: REFERENCE MATERIALS

Appendix A. Table of biotechnology products approaching commercialization

Crop	Trait category
Potato	Resistance to infestation by potato tuber moth
Squash	Resistance to a major viral pathogen
Maize	Resistance to stem borers
Cotton	Resistance to certain insects